Drug Utilization Review Board

Meeting Minutes

Thursday, April 13, 2023
7:15 a.m. to 7:55 a.m.
Google Meet

Board Members Present:

Eric Cannon, PharmD, FAMCP, Board Chair
Jennifer Brinton, MD
Judith Turner, DVM, PharmD
Katherine Smith, PharmD
Kumar Shah, MSc, PEng
Michelle Hofmann, MD
Neal Catalano, PharmD
Sharon Weinstein, MD
Susan Siegfreid, MD

Board Members Excused:

Colby Hancock, PharmD

Dept. of Health/Div. of Health Care Financing Staff Present:

Lisa Angelos, PharmD, Pharmacy Director
Bryan Larson, PharmD
James Stamos, Office Director
Jennifer Strohecker, PharmD, Medicaid Director
Joe Busby, RPh, MBA
Julie Armstrong, CPhT
Luis Moreno, PharmD
Ngan Huynh, PharmD
Stephanie Byrne, PharmD

University of Utah Drug Regimen Review Center Staff Presenter:

Monet Luloh, PharmD U of U DRRC

Other Individuals Present:

Amy Hale, Johnson & Johnson
Dave West
David Testerman, Change Healthcare
Heidi Goodrich, Molina Healthcare
Jason Bott, Eli Lilly
Miles Rooney, Change Healthcare
Paul Ford
Todd Dickerson, Jazz Pharmaceuticals
Valerie Gonzales, PharmD U of U DRRC

Meeting conducted by: Eric Cannon

1. **Welcome:** Ngan Huynh opened the meeting and reminded everyone who attended the meeting to identify themselves via meeting chat or by sending

an email to medicaidpharmacy@utah.gov. Ngan Huynh announced a quorum.

2. **Review and Approval of March Minutes:** Kumar Shah motioned to approve the minutes from March as drafted. Sharon Weinstein seconded the motion. Unanimous approval. Neal Catalano was not present for vote.

3. **Pediatric Pulmonary Arterial Hypertension:**
    a. **Information:** Monet Luloh, PharmD from the University of Utah College of Pharmacy Drug Regimen Review Center (DRRC) presented peer-reviewed research regarding pediatric pulmonary arterial hypertension treatment guidelines, considerations for prior authorization criteria, and utilization for approved therapies. Pulmonary arterial hypertension (PAH) is a rare disorder caused by vasculopathy of the pulmonary arterial vasculature and classified as group one out of five groups with additional sub-classes. Severity is determined by the World Health Organization Functional Class for Pulmonary Hypertension, six-minute walk distance test, and various laboratory assessments. Most persistent pulmonary hypertension of the newborn (PPHN) cases occur during infancy. Persistent PPHN is characterized as a sustained increase in pulmonary vascular resistance (PVR) with persistent hypoxemia. Persistent PPHN may be associated with various disorders. Therapies that have been approved by the Food and Drug Administration (FDA) for the treatment of PPHN include bosentan. Tadalafil, ambrisentan, macitentan, epoprostenol, treprostinil, and iloprost have unspecified approved ages. Treprostinil is also approved for non-pulmonary arterial hypertension indications. Micromedex states “evidence favors efficacy” for the off-label use of sildenafil in pediatrics. Recommendations for treatment guidelines were reviewed from the 2022 European Society of Cardiology and the European Respiratory Society. Calcium channel blockers are only recommended for children who have a positive air velocity transducer (AVT) response and are at least one year of age. Considerations for prior authorization criteria include separate diagnostic criteria for PAH in pediatrics and persistent PPHN in infants, allowing provider attestation when the use of calcium channel blockers (CCBs) is

inappropriate or removal of the criterion, omitting the requirements of WHO-FC II, III, or IV in order to receive PAH therapy because it may not be suitable for young children, extending re-authorization frequency to minimize treatment interruptions, removing the positive clinical response requirement because it may not be sensitive to nuances of the disease, or considering additional markers for improved disease severity and patient specific goals expressed by the provider, considering removal of previously failed PAH specific agents, and considering additional FDA approved indications and compendia-supported off-label uses. Twenty pediatric members used a PAH drug in the Medicaid Fee-for-service population in 2022 with a total of 144 claims.

b. **Board Discussion:** Luis Moreno, PharmD presented the updated proposed prior authorization criteria for Pulmonary Hypertension. Valerie Gonzales, PharmD from the University of Utah College of Pharmacy DRRC suggested clarifying the WHO functional class II, III, or IV criteria should only apply to Group 1. Sharon Weinstein, MD suggested placing the criteria under Group 1 and inquired why Group 2 was not included. Luis Moreno stated the medications on the prior authorization form do not pertain to Group 2. Katherine Smith, PharmD inquired if the prior authorization form is going to be used for pediatrics due to not meeting all criteria on the form the way it is listed. Jennifer Brinton, MD stated from a pediatrician's point of view the prior authorization criteria is clear with the recommended updates to the WHO functional class, class II, III, and IV only applying to adults.

Select requested medication(s):

Preferred products are bold. *Non-Preferred Product Criteria also applies to (non-bolded) products.*

☐ Adempas (riociguat) ☐ Adcirca (**tadalafil**) ☐ Alyq (**tadalafil**) ☐ Flolan (**epoprostenol**) ☐ Letairis (**ambrisentan**)

☐ Opsumit (macitentan) ☐ Orenitram (treprostinil) ☐ Remodulin (treprostinil) ☐ Revatio (**sildenafil**) ☐ **Tracleer** (bosentan)

☐ Tyvaso (treprostinil) ☐ Uptravi (selexipag) ☐ Veletri (**epoprostenol**) ☐ Ventavis (iloprost) ☐ Other: _____

Criteria for Approval: *(**All** criteria must be met)*

- ❑ Medication prescribed by, or in consultation with a pulmonologist or cardiologist.
- ❑ Diagnosis of pulmonary hypertension:
  - ❑ Group 1: pulmonary arterial hypertension
    - Patient has a history of WHO functional class (adult only): ☐ II ☐ III ☐ IV
  - ❑ Group 3: interstitial lung disease (Tyvaso only)
  - ❑ Group 4: chronic thromboembolic pulmonary hypertension (CTEPH) after surgical intervention or is inoperable (riociguat only)
- ❑ Indicate all of the following medications that the patient has trialed:

Nitric Oxide-cGMP Enhancers	Endothelin Receptor Antagonists	Prostacyclin Pathway Agonists	
☐ Adcirca (**tadalafil**)	☐ Letairis (**ambrisentan**)	☐ Flolan (**epoprostenol**)	☐ Uptravi (selexipag)
☐ Adempas (riociguat)	☐ Opsumit (macitentan)	☐ Orenitram (treprostinil)	☐ Veletri (epoprostenol)
☐ Alyq (**tadalafil**)	☐ **Tracleer** (bosentan)	☐ Remodulin (treprostinil)	☐ Ventavis (iloprost)
☐ Revatio (**sildenafil**)		☐ Tyvaso (treprostinil)	

Non-Preferred Product: *(Criteria above must also be met; and at least one of the following conditions must be met)*

- ❑ Trial and failure of preferred product, per Utah Medicaid's PDL, or prescriber must demonstrate medical necessity for non-preferred product. Details: _____ Chart Note Page #: _____
- ❑ Continuation of Therapy: Member has been treated with the requested non-preferred drug at a consistent dosage for at least 60 days in most recent 90 days and the prescriber indicates the prescribed medication will best treat the member's condition. Details: _____ Chart Note Page #: _____

NOTE:

- ❖ Per federal regulation, Medicaid does not reimburse for drugs used for the treatment of sexual dysfunction or erectile dysfunction. Pharmacies should dispense only those products with pulmonary hypertension NDCs.

Re-authorization Criteria:

Updated letter or updated chart notes supporting that the patient can benefit from the requested medication.

Authorization:

28 days for titration dosing (up to three (3) months for Uptravi), or maintenance dosing = six (6) months

Re-authorization:

Up to twelve (12) months

c. **Board Action:** Sharon Weinstein motioned to approve the prior authorization criteria with the proposed changes. Katherine Smith seconded the motion. Unanimous approval. Eric Cannon was not present for vote.

4. **Meeting Chat Transcript:**

00:00:32.438,00:00:35.438

Todd Dickerson: Thanks Joe. Todd Dickerson, Jazz Pharmaceutical

00:01:37.087,00:01:40.087
Amy Hale: Amy Hale, Johnson and Johnson

00:12:41.720,00:12:44.720
Eric Cannon: I need to step off for a few minutes and will be back shortly.

5. **The next meeting scheduled for Thursday, May 11, 2023** Weight Management.

6. **Public Meeting Adjourned:** Michelle Hofmann motioned to adjourn the meeting. Kumar Shah seconded the motion. Unanimous approval. Eric Cannon was not present for vote.

Audio recordings of DUR meetings are available online at: https://medicaid.utah.gov/pharmacy/drug-utilization-review-board?p=DUR%20Board%20Audio%20Recordings/